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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/336,672	06/17/99	HERRATH M	SCRIP1100

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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	5

DATE MAILED: 01/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/336,672	Applicant(s) Von Herrath
	Examiner WILLIAM SANDALS	Group Art Unit 1636

☒ Responsive to communication(s) filed on *Jun 17, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-31* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Specification

1. The use of the trademarks ACCUCHECK III and TWEEN have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

3. A sequence appears at page 40 which is not accompanied by a sequence identifier.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the

period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 112

4. Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of diabetes in a mouse model system, does not reasonably provide enablement for treatment of any autoimmune disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are drawn to a composition and method for treating or preventing an autoimmune disorder by administering a nucleic acid construct encoding at least one epitope from a self-antigen to an animal. While applicants have shown a method of treatment of diabetes in a mouse model system, they have not demonstrated a method of treatment of **any** autoimmune disorder. In order to do so, undue experimentation is required. Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors. Many of these factors have been summarized in *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

The Wands factors as they apply to the instant claimed invention are as follows:

a- The quantity of experimentation necessary to reduce the instant claimed invention to practice would involve a development of a method of treatment for each autoimmune disorder.

b- Guidance is provided which demonstrates a treatment of a mouse model system for diabetes, along with experimental data for the treatment of diabetes in a mouse model system. Only prophetic guidance is provided for other autoimmune disorders.

c- The nature of the invention is complex. Treatment or prevention of diabetes by gene therapy is still in a developmental stage, and as such is highly unpredictable.

d- The prior art has taught the gene therapeutic treatment of diabetes with replacement of cells which will produce insulin. Induction of immunologic anergy toward insulin producing cells has only been prophetically taught as described in Giannoukakis et al. at page 2107, column 2, where they state "[i]ntervention aimed at limiting islet damage will become plausible only when more satisfactory risk prediction protocols are developed. However, some safe preventive measures have already been explored in animal models and may eventually be applied to humans.

e- Giannoukakis et al. have taught the unpredictability of the claimed invention at page 2117 column 2 where they state "[a] better understanding of the genetics, the environmental triggers, and the immunopathology of type I diabetes, together with the factors affecting islet engraftment, as well as allogeneic and xenogeneic tolerance and protection from immune destruction, is necessary for these approaches to find clinical use."

f- Therefore, given the analysis above, it must be considered that the skilled artisan would have needed to have practiced considerable non-routine, trial and error experimentation to enable the full scope of the claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 8, 9, 17, 19, 20, 27, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 6, 17 and 27 recite the limitation "biological response modifier". "Biological response modifier" is not an art recognized term, and no definition is provided in the claims and specification to inform one of skill in the art exactly what is meant by this term. As a result the claim is vague and indefinite.

8. Claims 9, 19, and 29 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B **and** (emphasis added) C." See Ex parte Markush , 1925 C.D. 126 (Comm'r Pat. 1925).

9. Claims 9, 20 and 30 recite the limitation "regulatory element". "Regulatory element" is not an art recognized term, and no definition is provided in the claims and specification to inform

one of skill in the art exactly what is meant by this term. As a result the claim is vague and indefinite.

10. Claim 29 recites the limitation "biological response modifier" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1, 2, 5, 7-11, 13, 16-23 and 26-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Prud'homme et al.

Prud'homme et al. taught (see especially the abstract, the introduction and the figures) a nucleic acid which encoded a self-antigen in a plasmid construct under the control of a CMV promoter which was administered to a mouse diabetes type I model system to protect the mice from onset of autoimmune diabetes. The construct comprised a nucleic acid sequence which encoded an interferon gamma.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-9, 11-20 and 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/46253.

WO97/46253 taught (see especially the abstract, pages 13, 16, 17, 19-22, 35-37 and example 4) a nucleic acid which encoded a self-antigen in a plasmid construct under the control of a promoter which was administered to a mouse model system to protect the mice from onset of autoimmune disorders. The construct comprised a nucleic acid sequence which encoded cytokines.

14. Claims 1, 2, 5, 9, 11, 13, 16, 20, 22, 23 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ally et al.

Ally et al. taught (see especially the abstract and the figures) a nucleic acid in a plasmid which encodes a self-antigen, under the control of a promoter, which was administered to a mouse diabetic model system to produce anergy and prevent or treat diabetes in the mice.

15. Claims 1, 2, 9, 11-13, 16-18, 20, 22, 23 and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/06718.

WO 95/06718 taught (see especially the abstract, pages 1-7, 11 and examples 14-17) a method of treating an autoimmune disorder by administering a vector containing a nucleic acid which encoded a self-antigen where the subject may be a human and a nucleic acid encoding a cytokine such as interleukin or interferon may be coadministered.

16. Claims 1, 2, 5-7, 9, 11-13, 16-18, 20, 22, 23 and 36-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/24908.

WO 98/24908 taught (see especially the abstract, pages 33-36 and 39-53) the administration of a vector which contained a nucleic acid which encoded a self-antigen to treat autoimmune diseases and a nucleic acid encoding a cytokine such as interferon gamma may be administered.

17. Claims 1, 4, 11,12, 15, 16, 22, 25, 26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/21926.

WO 95/21926 taught (see especially the abstract, and pages 6-13) the administration of a plasmid vector which contained a nucleic acid which encoded a self-antigen, which may be myelin basic protein, to treat autoimmune diseases such as multiple sclerosis and the subject may be human.

Conclusion

18. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or

applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

William Sandals, Ph.D.

Examiner

January 14, 2000

ROBERT A. SCHWARTZMAN
PATENT EXAMINER